

**510(k) Summary for the Sorin Group Deutschland GmbH** JAN - 6 2011

(per 21 CFR 807.92 and

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>)

**1. SPONSOR/APPLICANT**

Sorin Group Deutschland GmbH

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Germany

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Contact: Renate Goebert

Date Prepared: January 4, 2010

**2. DEVICE NAME**

Proprietary Name: Sorin B-Care<sub>5</sub>

Common/Usual Name: Venous blood gas module for heart lung machine; perfusion monitoring device

Classification Name: Cardiopulmonary bypass, on-line blood gas monitor (21 CFR 870.4330; Product code: DRY)

**3. PREDICATE DEVICE/S**

- Dideco Data Master, K001388
- Sorin B-Care<sub>5</sub> (*Addition of an Optional Modular Accessory to the Stöckert S5 System*), K092463)

**4. DEVICE DESCRIPTION**

**• Physical description**

The Sorin B-Care<sub>5</sub> described in this 510(k) Premarket Notification is identical to the device that was cleared under K092463 and uses the same in-line sensors cleared under K001388.

**• How the device functions**

When switched on, the Sorin B-Care<sub>5</sub> progresses from warm-through initialization self test while resting on the holder. When self test is successful, Sat- (venous

saturation) and Hct- (hematocrit) values are displayed. The sensor is then mounted on the disposable connector in the extra-corporal circuit. The B-Care<sub>5</sub> alerts (alarms or warns) the user if laboratory reference values have not been stored for venous O<sub>2</sub> saturation and hematocrit.

- **Scientific concepts that form the basis for the device**

The Sorin B-Care<sub>5</sub> monitors blood values via the sensor head with two LED sources and a receiver in contact with the optical window integrated into the venous connectors. Temperatures are monitored using thermistors in the venous probes. The technology of the Sorin B-Care<sub>5</sub> is based on the technology of the Dideco Data Master (Sorin Group Italia is the parent company of Sorin Group Deutschland GmbH and was formerly known as Dideco).

- **Significant physical and performance characteristics of the device, such as device design, material used, and physical properties**

The B-Care<sub>5</sub> is used for determining oxygen saturation, hematocrit, and temperature in the venous blood circuit. Specifications are provided in B-Care<sub>5</sub> Operating Instructions.

## **5. INTENDED USE/INDICATION FOR USE**

The B-Care<sub>5</sub> is intended for use as a component part of or optional accessory to the Stöckert S5 system (or any compatible system using the S5 firmware versions of 3.0 or greater), during cardiopulmonary bypass for procedures up to six hours. The B-Care<sub>5</sub> is used exclusively for determining oxygen saturation, hematocrit value and temperature in the venous blood circuit.

## **6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S**

The technological characteristics of the B-Care<sub>5</sub> are identical to those reported to the FDA in K092463 and substantially equivalent to those of the Dideco Data Master (K001388). All are firmware-controlled systems using the same in-line connectors with integral sensor probes. All devices read the data external to the blood circulation and display data digitally; all are controlled via touchscreen. Venous saturation and hematocrit values are calibrated to reference (laboratory) values. All provide trending of values and allow the user to program alarm limits. However, the Dideco Data Master can be used independently of a heart lung machine console, whereas the B-Care<sub>5</sub> cannot be used independently and must be used connected to a Sorin/Stöckert heart lung machine console.

Sorin B-Care<sub>5</sub> and Data Master specifications for the following are identical: saturation resolution, saturation accuracy, hematocrit resolution, and temperature resolution.

There are some minor differences in the operational specifications but all are within clinically relevant ranges. For example, the saturation range for the B-Care<sub>5</sub> has a wider range (0%-100%) than the Data Master (40%-100%); the B-Care<sub>5</sub> hematocrit range is 0% to 100% while the Data Master hematocrit range is 15% to 50%; the B-Care<sub>5</sub> temperature range is 0°C to 50°C while the Data Master temperature range is 10°C to 45°C. These wider ranges allow the perfusionist to operate and detect the specified parameters at lower and higher levels.

## **7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE**

The Sorin B-Care<sub>5</sub> was tested in conjunction with the heart lung machine for safety in accordance with IEC60601-1 (with National Deviations), for electromagnetic compatibility in accordance with IEC60601-1-2, and performance according to a formal prospectively defined functional acceptance test. Testing of the Sorin B-Care<sub>5</sub> (hardware, firmware, and performance) has demonstrated that the Sorin B-Care<sub>5</sub> fulfills prospectively defined performance criteria and that the System meets user needs.

## **8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE**

Formal clinical testing of the Sorin B-Care<sub>5</sub> has not been performed. Therefore, this section does not apply.

## **9. SUMMARY OF OTHER INFORMATION**

No information other than that described was provided.

## **10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS**

Based on the non-clinical testing provided in this premarket notification, the Sorin B-Care<sub>5</sub> integrated with the Stöckert S5 performs in an identical manner as the B-Care<sub>5</sub> integrated with the C5, thus demonstrating that there are no differences and that the devices are substantially equivalent and perform in accordance with specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Sorin Group Deutschland GmbH  
c/o Ms. Rosina Robinson  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

JAN - 6 2011

Re: K103168

Trade/Device Name: Sorin B-Care<sub>5</sub>  
Regulation Number: 21 CFR 870.4330  
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor  
Regulatory Class: II  
Product Code: DRY  
Dated: October 26, 2010  
Received: October 27, 2010

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

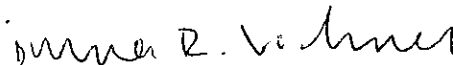
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21


CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

JAN - 6 2011

510(k) Number (if known): K103168

Device Name: Sorin B-Care<sub>5</sub>

Indications for Use:

The B-Care<sub>5</sub> is intended for use as a component part of or optional accessory to the Stöckert S5 system (or any compatible system using the S5 firmware versions of 3.0 or greater), during cardiopulmonary bypass for procedures up to six hours. The B-Care<sub>5</sub> is used exclusively for determining oxygen saturation, hematocrit value and temperature in the venous blood circuit.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use       
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Volmer  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K103168